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DIRECTOR'S OFFICE  
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 22 1985

Food and Drug Administration  
Rockville MD 20857

GROUP 120

RE: New Jersey Meniscal Bearing  
Knee Replacement  
Docket No. 85E-0296

JUL 18 1985

Charles E. Van Horn  
Director, Patent Examining Group 120  
U.S. Patent & Trademark Office  
• Washington, D. C. 20231

Dear Mr. Van Horn

This is in regard to the application for patent extension for U.S. Patent No. 4,309,778, filed by Bio-medical Engineering Trust, under Title II of Public Law 98-417, 35 U.S.C. § 156 et seq. The medical device claimed by the patent is the New Jersey Meniscal Bearing Knee Replacement, PMA P830055/S2.

A review of the Food and Drug Administration's official records indicates that the New Jersey Meniscal Bearing Knee Replacement, the product identified by the patent extension application, was subject to a regulatory review period before its commercial marketing or use, as required by 35 U.S.C. § 156(a)(4). Our records also indicate that PMA P830055/S2 represents the first commercial marketing or use of this product, as required by § 156(a)(5) of the law.

If you conclude that the subject patent is eligible for patent extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson  
Director, Health Assessment  
Policy Staff

cc: John G. Gilfillian III  
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